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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/187,669	11/05/1998	EDUARDO MARBAN	47728	3339

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EXAMINER
LEFFERS JR, GERALD G

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 11/05/2002 17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/187,669	Applicant(s) MARBAN, EDUARDO	
	Examiner Gerald G Leffers Jr.	Art Unit 1636	

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 August 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *16-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15 and 29-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt is acknowledged of applicant's amendment, filed 8/5/02 as Paper No. 16. In Paper No. 16 several claims were amended (claims 1-2, 7, 14, 29 and 31). Claims 1-31 are pending in this application with claims 16-28 withdrawn from consideration as being directed towards a nonelected invention.

Any rejection of record in the previous office action (Paper No. 15) that has not been addressed in this action is withdrawn. **Because each of the new grounds for rejection made in this action was necessitated by applicants' amendment of the claims in Paper No. 16, this action is FINAL.**

Election/Restrictions

Claims 16-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8, filed 3/2/01.

This application contains claims drawn to an invention nonelected with traverse in Paper No. 8. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (i.e. page 21, line 24). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. It is

noted that applicants attempted to amend the specification in Paper No. 16 to correct the situation. However, this amendment did not delete the hyperlink from the specification. Further, the amendment was not entered because it did not specify how the specification was to be amended (e.g. "insertion of the phrase --Genbank is also available on the internet.-- at page 21, lines 23-24, after the words....").

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Each of the claims comprises the limitation "...wherein, expression of the drug target protein results in an increase or decrease in expression of the drug target protein when a candidate drug is administered to the host cells as compared to the expression in host cells to which a candidate drug is administered but in which the drug target protein has not been introduced." This phrase constitutes new matter on at least two grounds. First, the phrase casts the claimed method in terms of predicting the effect of a drug candidate compound on the *expression* of the drug target protein. There is no support in those sections of the specification cited in applicant's response in Paper No. 16 as providing support for changes to claim 1 for this

concept. The specification only appears to provide support for using somatic gene transfer to express a target gene protein in a host cell and observing the effect of the compound on the target protein *function* (e.g. measuring the effects on an ion channel whose expression is mediated by somatic gene transfer). Secondly, there is no support in the specification for the step of comparing expression of the protein in a test cell to that in a control cell. Therefore, for at least these reasons, the cited phrase is impermissible NEW MATTER.

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 2 further comprises the limitation "...wherein the drug target protein expression is modulated when a candidate drug compound is administered to a host cell, in which the drug target protein has been introduced, thereby identifying a target of the drug candidate compound." This phrase links identification of a target protein of a drug candidate compound to an alteration in the target protein *expression* in response to the drug compound. There is no literal support in the specification for this limitation. Therefore, this limitation is also impermissible NEW MATTER.

Claims 7-15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 7-15 are directed towards a method of "detecting a potential drug target protein" and comprises the newly added steps of "...administering a candidate drug compound to the host cells; and, determining the expression of the drug target protein expressed in the host cells." There is no support in the specification as filed for a method of detecting a potential drug target protein wherein the potential drug target protein is detected by determining the *expression* of the drug target protein is response to administration of a drug compound.

Claims 29-31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Each of the claims comprises the newly added limitations "...administering to the cells a candidate drug compound; wherein the candidate drug compound modulates the expression of the drug target protein; and analyzing the expression of the drug target protein as a result of administering the candidate drug compound; and thereby predicting the effect of the drug candidate compound." These limitations link administering the candidate drug compound to cells to monitoring levels of expression of the drug target protein to predicting the effect of the drug candidate compound. There is no support in the specification as filed for linking *expression* of the drug target protein in response to a candidate drug to predicting the effects of the drug candidate. Therefore, the newly added limitations are impermissible NEW MATTER.

Claim 31 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 31 comprises the limitation "...analyzing the expression of the modified drug target protein in cells, tissue or organ to which the candidate drug has been administered to determine potential drug target proteins." There is no support in the specification as filed for linking analysis of expression of a modified drug target protein to determining potential target proteins. Therefore, this newly added limitation is impermissible NEW MATTER.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in that the metes and bounds of the phrase "...wherein, expression of the drug target protein results in an increase or decrease in expression of the drug target protein when a candidate drug is administered to the host cells as compared to the expression in host cells to which a candidate drug is administered but in which the drug target protein has not been introduced..." are unclear. It is unclear how one can monitor the expression of a drug target protein in a control cell when the drug target protein has not been introduced. It

would be remedial to amend the claim language to clearly indicate how one can assay for the drug target protein in the control cell population.

Claim 2 is vague and indefinite in that the end result of the claimed method, "...thereby identifying a target of the drug candidate compound," does not recapitulate the preamble of the claim. The claim is directed towards predicting the effect of a drug candidate compound but ends by identifying a target of a drug candidate compound. It is unclear as the claim is written whether by identifying a target of the drug candidate compound one has completed the claimed method of "predicting the effect of" the drug compound.

Claim 31 is vague and indefinite in that the metes and bounds of the phrase "...analyzing the expression of the modified drug target protein in cells, tissue or organ to which the candidate drug as been administered to determine potential drug target proteins..." are unclear. First, the phrase makes it unclear whether by "determining potential drug target proteins" one has obtained the stated goal of the claimed method of "mimicking one or more effects of a drug candidate compound". The end result of the claim does not recapitulate the preamble of the claim. Secondly, it is unclear how analyzing expression of the modified drug target protein results in determining other potential drug target proteins. This appears to be nothing more than a desired result without any positive action method steps recited to achieve the desired objective of "determining potential drug target proteins".

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gerald G Leffers Jr.
Examiner
Art Unit 1636

ggl
November 4, 2002

TERRY MCKELVEY
PRIMARY EXAMINER